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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,421	03/12/2004	John Devane	09487.0003-00	6571

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,421	DEVANE, JOHN	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,9,10,13-37,39-42 and 44-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6, 9, 10, 13-37, 39-42, 44-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's Reply filed August 5, 2008 is acknowledged. Claims 11 and 12 are presently canceled. Claims 1, 3-6, 9, 10, 13-37 and 44-77 remain under consideration.

A substitute specification is noted.

Applicant's arguments presented in response to the last Office Action have been considered. Those objections and/or rejections not herein reiterated are withdrawn. The following objection and rejections constitute the only objection and rejections presently applied to the instant claims.

In the last Office Action claims 39 and 42 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant argues minimizing a given side effect is a particular characteristic of certain embodiments of the invention, and claim 42 specifies a dose of the modified-release formulation that may be administered to achieve the peak:trough plasma level ratio

Intended use confers no patentable weight to composition claims. See *In re Hack*, 114 USPQ 161 (CCPA 1957).

Claims 39 and 42, respectively, recite an intended use, such as minimizing a side effect or a desired dosing regimen, without reciting a specific chemical or physical property of the formulation of claim 30 from which they depend. Accordingly, claims 39 and 42 do not further limit the subject matter of claim 30, and the objection of record is maintained.

Claims 1, 3-6, 9-37, 39-42 and 44-77 were rejected under 35 U.S.C. 112, first paragraph, in the last Office Action as failing to comply with the written description requirement. It was asserted the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant argues that the disclosure at paragraphs [0015] and [0016] permits a person of ordinary skill to immediately envisage the present invention. Applicant urges the description provided in the specification and the hypothetical examples detail how a person of ordinary skill would determine improvement of symptoms, and Example 6 describes how to obtain samples from patients from which individual plasma concentration curves can be constructed to determine pharmaceutical parameters such as a peak:trough ratio.

Applicant's argument is not found persuasive, and the rejection of record under 35 U.S.C. 112, first paragraph, of claims 1, 3-6, 9, 10, 13-37 and 44-77 is maintained. Possession may be shown by an actual reduction to practice of the claimed invention. In this case, an adequate written description of the invention has not been set forth such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. The inventor has failed to present a reduction to practice by constructing embodiments that meet all of the limitations of the claims, as well presenting a reasonable expectation that the invention as a whole will work. The

specification lacks sufficiently detailed, relevant description that provides evidence that Applicant was in possession of the claimed invention.

In the instant case Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. In Example 1, page 74 of the specification, a hypothetical situation is described drawn to subjects diagnosed with increased gastrointestinal motility due to irritable bowel syndrome (IBS). On pages 82-83 of the specification in Example 7, another hypothetical situation is described for subjects diagnosed with diarrhea-dominant irritable bowel syndrome. Applicant states the formulations disclosed in the specification comprising N-2,3,3-tetramethylbicyclo-[2.1.1]heptan-2-amine demonstrate efficacy in improving IBS symptoms and a dissociation of gastrointestinal motility effects from effects on other systems, including blood pressure, heart rate, vision and bladder function. No such conclusions with respect to "minimizing at least one side effect associated with the administration of a conventional formulation of N-2,2,3-tetramethylbicyclo-[2.1.1]heptan-2-amine", as recited in instant claim 5, are noted. The skilled artisan in gastroenterology would reasonably require a more detailed description of minimization of said side effects. There is no description in the instant specification to provide support for minimizing any side effect, such as those relating to heart rate, blurred vision, bladder function or blood pressure.

Further, there is no description in the instant specification to provide support for any of the claimed pharmacokinetic and pharmacodynamic limitations of the present claims. Although working examples are not required, in the present case there is no

description that would provide support to one of ordinary skill in the art an embodiment that meets all the limitations of the claims.

The MPEP states that the purpose of the written description is to ensure that the inventor had possession, as of the filing date of the application, of the subject matter defined by the claims. A required description of the numerous and specific pharmacokinetic and pharmacodynamic limitations recited in the claims is absent. One skilled in the art would not have immediately envisaged the claimed limitations in the instant methods, formulations and transdermal formulations.

In the last Office Action claims 1, 3-6, 9-37, 39-42 and 44-77 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shytle et al., WO 00/35280 or Shytle et al., WO 00/35279, in view of Summers et al., Gastroenterology (Abstract). It was asserted Shytle teaches the administration of mecamylamine (N-2,3,3-tetramethylbicyclo-[2.1.1]heptan-2-amine), or an optical isomer thereof, in the treatment of gastrointestinal motility disorders, such as Crohn's disease, or spasmogenic intestinal disorders, such as irritable bowel syndrome. See claims 54 and 62, pages 28 and 29. Transdermal administrations are disclosed in claims 55 and 63. Dosages are taught on page 12, as a range of about 0.001 mg/kg to about 6 mg/kg per day of exo-S-mecamylamine. Compositions may be formulated to provide rapid, sustained or delayed release of the active agent, as well as by controlled-release means. Combinations with multiple release layers are presently conventional formulations. Such characterizations encompass the "modified-release formulation" requirement of instant claims 1 and 30. Shytle teaches the optically active forms of mecamylamine, as well as

the racemic mixture on pages 2-4. Shytle teaches optical purity is important in that one isomer may be active while the other is inert. One isomer may produce an adverse effect while the other does not. In the case of mecamylamine, little or no difference in potency or efficacy is noted. In view of the well documented adverse effects resulting from the administration of racemic mecamylamine, the skilled artisan is provided motivation to seek an enriched or pure (R) or (S) enantiomer with which less, or no, adverse effects may occur.

Applicant argues Shytle fails to teach numerous pharmacokinetic and pharmacodynamic elements of the present invention, as well as a disclosure that one may interpret as "spasmogenic intestinal disorders."

Summers teaches significant inhibition of gastrointestinal propulsion – herein interpreted to be characteristic of spasmogenic intestinal disorders - in a mammalian model following mecamylamine administration. Such inhibition would have reasonably been a desired property in treating a functional bowel disorder, such as diarrhea-dominant irritable bowel syndrome, wherein patients suffer from an abnormal increase in gastrointestinal motility.

Determining optimal pharmacokinetic and pharmacodynamic parameters is well within the purview of those skilled in the art of formulation chemistry through no more than routine experimentation. Applicant has merely discovered unknown properties for an old compound. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc.,

51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of unknown properties, i.e., pharmacokinetic properties, which are inherently present in the prior art does not make the present claims patentable.

Applicant argues inherency may be used in an anticipation rejection, but it is not appropriate under obviousness.

In this regard, Applicant is directed to MPEP 2112. Inherent disclosures may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. See *In re Napier*, 34 USPQ2d 1782 (Fed. Cir. 1995).

The rejection of record of claims 1, 3-6, 9, 10, 13-37 and 44-77 under 35 U.S.C. 103 is maintained.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 18, 2008

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614